UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/429,331	10/28/1999	LISA A. PAIGE	PAIGE=1D	5796

1444 7590 11/30/2006

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/429,331	PAIGE ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 1006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *135-139,142-146,148-153 and 155-157* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *135-139, 142-146, 148-153 and 155-157* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 135-139, 142-146, 148-153 and 155-157 are pending and under examination.

Withdrawn Rejection

The provisional obviousness double patenting rejection over the now abandoned application S.N. 10/346,162.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 135-139, 142-146, 148-153 and 155-157, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The "optional" step (b) is not supported in the as-filed specification. The specification does not recite that the

estrogen receptor has not been reacted with the plurality of reference compounds.

Applicants point out that claim 135, as amended, is supported at e.g., page 37, lines 14-22.

The cited sections e.g., page 37 while providing supports for the term "unliganded" however, does not provide support for the "optional" step(b). [The context of section e.g., page 37 is so confusing as it correlates to the claims.]

Claim Rejections - 35 USC § 112, second paragraph

Claims 135-139, 142-146, 148-153 and 155-157, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention and reiterated below only for those rejections that are maintained.

A). Claim 136 is unclear as to what constitutes a panel-based descriptor, especially in the absence of positive definition or recitation in the specification.

Response to Arguments

Applicants rely at page 46, lines 21-11 of the specification to clarify the phrase "panel-based descriptors".

Applicants further rely at page 46, line 31 through page 47, line 6 that describe a "descriptor" (also known as a parameter, character, variable or variate) as a numerically expressed characterization of a compound (which may be a protein, or a protein ligand) which helps to distinguish that compound from others.

In reply, the cited section refers to a Biokey-based descriptors i.e., a trademark panel, the constitution of which is not defined in the specification. It is not clear in what sense the descriptors are based on said trademark panel. While applicants are permitted to be his own lexicographer however, it carries with it the connotation that he will use terms consistently throughout his patent. Porter v. Farmers Supply Services Inc., 228 USPQ 4. Also with terms that is consistent and conventional in the art. Applicants used of the terminologies that do not correspond to those in the prior art and specification not only provides for confusion and ambiguity but also renders the claim unsearchable over the prior art. For example, in what sense is a descriptor numerically expressed? Applicants have not provided any evidence by prior art, as to the use of the term descriptor(s) and panel-based descriptors instead of the conventionally used proteins and array, respectively as used in the art.

B). There is no definition for Xaa in claim 148.

Response to Arguments

Applicants point out that there is no requirement that claim terms must be specifically defined in the specification, particularly if the term adequately informs the skilled artisan of the metes and bounds of the claims. One of ordinary skill in the art would recognize that the term "amino acid" is known in the art to include natural amino acids and unnatural amino acids.

In response, terms use in a claim do not stand in a vacuum but must be read or interpreted in light of specification, so read, one skilled in the art can determine scope of the instant claimed method. There is nothing in the specification that defines said Xaa as natural or unnatural amino acids. For example, what would be considered unnatural amino acids in the context of the claimed descriptors or of the specification? Thus, one of ordinary skill in the art would not recognize what an unnatural amino acids applicants are referring thereto especially, since applicants stated above that the terms are not specifically defined in the specification.

The newly amended claims are rejected as follows:

I. The claimed method steps are confusing and unclear as to what the method steps include or preclude. If step 1(b) were

optional, then all the subsequent step 1(c) through step 3 would be non-existent as well as claims 136-139 and all the other dependent claims. Further, if step (b) is optionally then steps (c) and (d) "said reference conformation" lacks antecedent basis of support from the preceding statement.

Non sequitur for "***the*** unliganded estrogen receptor". (Claim 135).

Double Patenting

Claims 135-139, 142-146, 148-153 and 155-157 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 6 of U.S. Patent No. 6,617,114 ('114 Patent) for reasons set forth in the last Office action.

Response to Arguments

Applicants submit that the specific recitation of the method of predicting the receptor-modulating activity of a test compound when bound to a receptor as recited in claims 135-139, 142-146, 148-153, and 155-157 of the subject application is not disclosed in claims 1, 2 and 6 of the '114 Patent. Rather, claims 1, 2, and 6 of the '114 Patent are directed to a method of identifying a ligand that can mediate the biological activity of a target protein. Applicants submit that the instant claims recite that the receptor-mediated activity of a test compound

bound to a receptor can be predicted by using a panel to obtain a fingerprint corresponding to how the test compound interacts with the receptor in its various panel-modified conformations. The similarity of the fingerprint of the test compound to the fingerprint of a reference compound of known biological activity can then be calculated and used to predict the bioactivity of the test compound. This feature, namely, predicting the receptor-modulating activity of a test compound when bound to a receptor, is believed to patentably distinguish the current claims.

In reply, is this merely a difference in semantics? Predicting is synonymous with identifying i.e., a modulating compounds' effect to a target. The claims are not read in vacuum but read in the light of the specification. So read, the specification at page 18, lines 9-17 states:

> This method provides a simple and consistent means for identifying and characterizing modulators of receptor activity, using 'BioKey' oligomers (especially peptides) to probe receptor conformation. It can be used as a tool in both primary and secondary screens for compounds that modulate the activity of a receptor. In some embodiments, the method is also completely in vitro so the activity of a compound can be assessed without using a cell based assay, let alone a whole animal assay.

A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. If all applicants are doing is predicting whether a compound would possess an effect or activity, then it appears that applicants have not successfully reached a conclusion. But still searching for a method that would produce a compound of desired effect or activity. It is no wonder that the specification provides only proposals as to how the method can be achieved.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
November 27, 2006